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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,179	03/12/2004	Manoj Kumar	DOC0057PA/DCS074/GC792-4	8989
7590	01/25/2005		EXAMINER	
DINSMORE & SHOHL LLP One Dayton Centre Suite 500 One South Main Street Dayton, OH 45402-2023			KOSAR, ANDREW D	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 01/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,179	KUMAR ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 December 2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-33 is/are pending in the application.
 4a) Of the above claim(s) 2,4-14 and 16-33 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1 and 3 is/are rejected.
 7) Claim(s) 15 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 12 March 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/9/04; 8/16/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-33 are pending.

Election/Restrictions

Applicant's election of Group II in the reply filed on December 1, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants have indicated that SEQ ID NO:19 is the elected species of Group II, and is found in Claim 15. Accordingly, Group III (Claim 15) has been rejoined with Group II for examination, as Group II/III.

Claims 2, 16-30, 32, and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 1, 2004.

The Examiner has determined that SEQ ID NO:19 is readable upon claims 3, 4, 5, 15, generic claims 12-14 and 31, and

Claims 10 and 11 have been withdrawn from further consideration as not reading upon the elected species, SEQ ID NO:19.

The restriction is still deemed proper and made FINAL.

Claims 1, 3-9, 12-15, and 31 have been examined on the merits.

Allowable Subject Matter

The elected species SEQ ID NO:19 has been found to be free of the prior art.

The following is a statement of reasons for the indication of allowable subject matter: The prior art alone, or in combination, neither suggests or renders obvious the peptide of SEQ ID NO:19, a silk-elastin protein polymer (SELP), identified as SELP-47K. The prior art teaches various SELPs but does not teach the instant SEQ ID NO:19.

Examiner Elected Species

The Examiner has extended the search to the following species: (QAQGDGADAGQP)₂. The peptide is readable upon generic claim 3, and linking claim 1.

Claims 4-9, 12-14, and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claim 15 is objected to as depending from a rejected claim.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the pictures are extremely dark, i.e.- the contrast of the images is such that the images appear solid black. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*,

(4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to a personal care composition comprising a repeat sequence protein polymer and a carrier or excipient.

(1) Level of skill and knowledge in the art:

The level of skill and knowledge in the peptide arts is high.

(2) Partial structure:

The protein (peptide) of the composition is required to be 'a repeat sequence polymer' and the claim and specification are silent to required essential components, e.g.- a specific core peptide component. The specification provides several SELP variants in the tables and specification. The specification is silent to the myriad of compounds embraced by the claim.

(3) Physical and/or chemical properties:

The claim and specification are silent as to specific physical and/or chemical properties of the repeat sequence protein polymer embraced by the claim, so long as it has a repeat sequence. The specification provides physical and chemical properties of several SELPs in the tables and specification, but is silent to the properties of the myriad of compounds embraced by the claims.

(4) Functional characteristics:

The claims and specification are silent to the functional characteristics of the infinite peptides which are embraced by the instant claim. The specification only provides that SELPs, compounds which are one specie embraced by the claim, have desirable characteristics imparted from silks durability and elastins flexibility.

(5) Method of making the claimed invention:

The specification and art provides that peptides are synthesized in cell culture, or through synthetic routes.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim 1 is a broad generic, with respect to all possible compounds encompassed by the claims. The possible structural variations of the repeat sequence protein polymer are limitless to any class of peptide, so long as it has some form of a repeating unit. In essence, the repeat may be as simple as, though not limited to, a single amino acid being found twice within a protein sequence. Accordingly, all peptides would be embraced by this claim, so long as they are in a personal care composition. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, the claims are silent to functional characteristics, other than the properties a portion may have, and further, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. While having written description of SEQ ID NO:19, SELP-47K, and the compounds identified

in the specification tables and/or examples, the specification is void of any peptides, proteins, or molecules that qualify for the functional characteristics claimed as the protein polymers with functional characteristics that qualify.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (Affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,614,194 ('194).

The instant claims are drawn to a personal care composition comprising a repeat sequence protein polymer of the formula $T_y[(A_n)_x(B)_b(A'_n)_x'(B')_b'(A''_n)_x'']T'_y$, wherein y, y', x, x', x'' can all be 0 in one embodiment, irrespective of what embodies T, T', A, A',

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or A''. In this embodiment, y, b, and b' are each 1, and B and B' are the same peptide sequence. Reduction of the formula results in an embodiment (B)(B'), or simply B₂.

'194 teaches the sequence (QAQGDGADAGQP) (claim 5) repeated at least twice (claim 4) in a physiologically acceptable carrier (claim 8). The composition is a vaccine. A vaccine is a personal care composition.

As such, claims 1 and 3 are anticipated by '194.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5945086; US 6017534; US 5606019; US 5723588; US 5770697; US 5808012; US 6018030; US 6355776; US 20020045567; US 6380154; US 20030176355; US 6033654; US 6140072; US 6184348; US 20020045567; US 6380154; US 6423333; US 20030104589; US 20030176355;

The following art is of relevance, though not prior art.

US 20040180027; US 20040180027; US 20040228913; US 20040234609.

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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